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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,614	03/11/2004	Jose Luis Moctezuma de la Barrera	29997/064	6202

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MCCRACKEN & FRANK LLP
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CHICAGO, IL 60606

EXAMINER

CHAO, ELMER M

ART UNIT	PAPER NUMBER
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3737

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/798,614

Applicant(s)

MOCTEZUMA DE LA BARRERA ET AL.

Examiner

Elmer Chao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/14/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. **Claims 19, 22, 25, 45, and 55** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 19, 22, 45 and 55 recite "...attached to the anatomical structure..." and claim 25 recites "...is fixedly mounted to the outer surface of the body...". In all cases the claims positively recite a part of the human body, and therefore are directed to nonstatutory subject matter. The Examiner suggests alternative language such as "adapted to be attached", "is capable of being fixedly mounted", etc. Appropriate action is required.

Drawings

3. The informal drawings are not of sufficient quality to permit examination because the drawings include handwritten numerals. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. **Claims 1-4, 21, 23, 39-42, 44-46, 47-51, 56-60, 63, 75, 76, and 78** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 18-25, 30, 49-50, 52-55, 71-76, 92-98, 108-113, and 132-136 of copending Application No. 10/798,677. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present

application claims are merely broader than the copending application claims (see *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. **Claims 16-18, 20, 52-54, 71-73, 75** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 22-25, 30, 53-55, 73-76, 94, and 111-113 of copending Application No. 10/798,677 in view of *Danisch* (U.S. 5,321,257). Application No. 10/798,677 does not teach a fiber and anchor, wherein the fiber includes a serrated portion covered by a light absorbent material. However, *Danisch* '257 teaches the use of a single or multiple fiber optic devices (Fig. 12; col. 6, lines 20-39), with a serrated light emission surface extending along one side of the fiber (col. 2, lines 36-57; claim 3), connected to a retrieval system (Fig. 1, Item 16), wherein an exemplary application would necessitate anchoring of the fiber (Fig. 16; col. 7, lines 34-49). It would have been obvious to a person of ordinary skill in the art at the time of the invention to use a fiber optic device to sense the position of an anatomical structure in order to provide a temperature-resistant and dynamic range of measurement (for motivation see col. 9, lines 49-68).

This is a provisional obviousness-type double patenting rejection.

7. **Claims 19, 22, 55, 74, 77** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 22-25, 30, 53-55, 73-76, 94, and 111-113 of copending Application No. 10/798,677 in view of *Danisch* '257, further in view of *Bartlett* (U.S. 5,441,502). The copending

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Application and Danisch '257 do not teach a means comprising a pin. However, Bartlett '502 teaches anchoring means comprising of pins (abstract). It would have been obvious to a person of ordinary skill in the art at the time of the invention to use pins to anchor the fiber optic sensors or magnetic sensors to an anatomical structure in order to easily remove the pins after use, as often used in bone attachment applications (for motivation see col. 4, lines 31-48; col. 5, lines 3-9).

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1-8, 13, 14, 24, 27-32, 37-43, and 56-62** are rejected under 35 U.S.C. 102(b) as being anticipated by Bova et al. (U.S. 6,390,982). Bova '982 teaches a method of determining a change in position (col. 6, lines 45-64) using a surgical navigation system (Fig 2, Item 28); a substrate capable of being removably mounted to an outer surface of a body (Fig 2, Item 24), wherein the body includes a bony anatomical structure (Fig 2, see spinal cord illustration beneath Item 22); a sensor of three LEDs attached to the substrate that can be tracked by the surgical navigation system (Fig 2, Item 26); a positional device attached to the substrate that determines a position of the anatomical structure, wherein the positional device is an ultrasonic

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imaging device (Fig 2, Item 22) capable of 3D imaging and containing an array of multiple ultrasonic transducers (col. 2, lines 42-50; col. 6, lines 25-33); a first circuit for calculating a global position of the anatomical structure by correlating a position of the sensor and the position of the anatomical structure (Fig 2, Item 20; col. 6, L36-44); a second circuit for displaying the global position of the anatomical structure on a display unit (Fig 2, Item 20; col. 6, lines 65-57).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over Bova '982 in view of Smith et al. (U.S. 2004/0097807). Bova '982 teaches the limitations as discussed above. Bova '982 does not teach using adhesive to mount the substrate onto the surface of the body. However, Smith '807 teaches using a coupling adhesive to mount an ultrasonic probe onto the surface of a body (abstract). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Bova '982 to use a coupling adhesive to mount the substrate to the surface of the body in order to non-invasively attach the probe to the patient, facilitate acoustic coupling (abstract), and not require other mechanical means to attach the probe to the surface of a patient (col. 1, lines 50-62).

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12. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Bova '982. Bova '982 teaches the limitations as discussed above. Bova '982 does not teach the substrate being 5cm in width and 5cm in length. However, the limitation of the substrate being approximately 5cm by 5cm is a design choice given that the Applicant has not provided any novel reasoning behind the choice of dimensions. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Bova '982 to similarly specify a substrate to be approximately 5cm by 5cm so that the ultrasonic imaging device can fit for a variety of different anatomical structures and still be fixedly attached to the surface of a patient.

13. **Claims 15-18, 20, 47-54, 70-73, 75** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bova '982 in view of Danisch (U.S. 5,321,257). Bova '982 teaches all of the above limitations. Bova '982 does not teach the use of a fiber optic device to sense position. However, Danisch '257 teaches the use of a single or multiple fiber optic devices (Fig. 12; col. 6, lines 20-39), with a serrated light emission surface extending along one side of the fiber (col. 2, lines 36-57; claim 3), connected to a retrieval system (Fig. 1, Item 16), wherein an exemplary application would necessitate anchoring of the fiber (Fig. 16; col. 7, lines 34-49). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Bova '982 to use a fiber optic device to sense the position of an anatomical structure in order to provide a temperature-resistant and dynamic range of measurement (for motivation see col. 9, lines 49-68).

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14. **Claims 21, 23, 44-46, 76, 78** is rejected under 35 U.S.C. 103(a) as being unpatentable over Bova '982 in view of Schneider (U.S. 6,073,043). Bova '982 teaches the limitations as discussed above. Bova '982 does not teach using a magnetic sensor and a magnetic transmitter as the positional device. However, Schneider '043 teaches using a magnetic sensor and transmitters to determine the position and location of a remote object (abstract), wherein the object can be a medical device and the operation zone is within a patient (col. 4, lines 42-63). It would have been obvious to a person of ordinary skill in the art at the time of the invention to use the magnetic sensor and transmitter in order to determine position with precision and without requiring multiple bulky structures (for motivation see col. 3, lines 44-55).

15. **Claims 19, 22, 55, 74, 77** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bova '982 in view of Danisch '257, further in view of Schneider '043, further in view of Bartlett (U.S. 5,441,502). Bova '982 and Danisch '257 teach the limitations as discussed above. They do not teach the anchoring means comprising a pin. However, Bartlett '502 teaches anchoring means comprising of pins (abstract). It would have been obvious to a person of ordinary skill in the art at the time of the invention to use pins to anchor the fiber optic sensors or magnetic sensors to an anatomical structure in order to easily remove the pins after use, as often used in bone attachment applications (for motivation see col. 4, lines 31-48; col. 5, lines 3-9).

16. **Claims 63-66, 68, and 69** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bova '982 in view of Sirimanne et al. (U.S. 6,356,782 B1). Bova '982 teaches the limitations as discussed above. Bova '982 does not teach placing a

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resorbable sonic reflective ball composed of air next to the anatomical structure.

However, Sirimanne '782 teaches placing resorbable sonic reflective balls composed of air next to an anatomical structure (abstract; col. 2, lines 54-65; col. 8, lines 43-54; Fig. 2B, Item 152). It would have been obvious to a person of ordinary skill in the art at the time of the invention to use sonic reflective balls so as to determine the location, orientation, and periphery of an anatomical structure (for motivation see col. 1, lines 10-20).

17. **Claims 9-12, 33-36, and 67** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bova '982 in view of Sirimanne '782, further in view of Cosman (U.S. 6,405,072 B1). Bova '982 and Sirimanne '782 teach the limitations as discussed above. Bova '982 and Sirimanne '782 do not teach placing three markers next to the anatomical structure. However, Cosman '072 teaches placing three markers on an ultrasonic scanner (col. 14, lines 30-42; Fig. 7, Items 131A-C). It would have been obvious to a person of ordinary skill in the art at the time of the invention to implant at least three sonic reflective balls since three markers are necessary for the ultrasound system to detect in three dimensions the orientation of the anatomical structure (for motivation see col. 14, lines 30-33).

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EC
12/27/2006


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